

**REMARKS/ARGUMENTS**

Claims 1-13 were pending in the instant application. Claim 1 has been amended to include the elements of previous claims 2, 3 and 10, plus the most preferred biological targets specified at [0051] in the specification of the application. As a consequence, claims 2, 3, 5, 9, 10 and 12 have been cancelled. Claim dependencies for claims 4, 6-8 and 11 have been corrected. Therefore, the amendments to claims 1, 4, 6-8, and 11 do not add new matter. Applicants respectfully request that the amendments be entered.

Upon entry of the above-made amendments claims 1, 4, 6-8, and 11 will be pending in the current application.

The following remarks, in conjunction with the above amendments, are believed to be fully responsive to the Office Action.

**1. Information Disclosure Statement**

Applicants note that the previous IDS omitted to supply copies of the foreign patent applications. Copies are now provided.

**2. Claim Rejections 35 USC §101.**

Claims 9 and 13 stand rejected because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Applicants note that Claim 13 had already been cancelled. In the light of the cancellation of Claim 9, this objection is believed moot.

**3. Claim Rejections 35 USC §112.**

Claims 1-13 stand rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement.

Claim 1 is not to a method of optical imaging of lung cancer, in which the contrast agent is defined by Formula I. The claim is no longer an optical imaging contrast agent claim *per se*. Hence, it can no longer be argued that the claim pertains to compounds defined only by their function. In addition, the claim scope has been limited to the most preferred biological targets described in the specification at [0051].

Applicants contend that the specification provides sufficient information for the person skilled in the art to reproduce the method of amended claim 1. The specification provides suitable optical reporters; a description of suitable optical imaging techniques at [0090] of the specification; plus a description of targeting molecules and methods of labelling them with optical reporters. The person skilled in the art can either use the contrast agents described in the specification, or generate new ones. Applicants suggest that the claim scope for such an optical imaging method claim should not be limited by the possible future advent of new targeting molecules. If person skilled in the art has available a compound with affinity for one of the targets described, then labelling such a compound with an optical reporter is taught by the present specification.

The revised claims are therefore believed to comply with 35 USC §112, first paragraph and Applicants contend that this rejection of claims 1, 4, 6-8, and 11 should be withdrawn.

#### **4. Claim Rejections 35 USC §102**

Claims 1-13 are rejected under 35 USC 102(b) as being anticipated by Weissleder *et al.* to US 2003/0044353 (Weissleder). Claims 1-9 and 12 stand rejected under 35 USC 102(b) as being anticipated by Klaveness *et al.* to US 6,610,269 (Klaveness). Claims 1-3 and 6-13 stand rejected under 35 USC 102(b) as being anticipated by Luiken to US 2001/0055566 (Luiken).

##### **4.1 Weissleder (US 2003/0044353).**

Claims 1-13 stand rejected as lacking novelty over Weissleder.

Applicants point out that claim 1 is now limited to a method of optical imaging of lung cancer, with particular biological targets defined (cathepsin L, caspase-3, HER2/epidermal growth factor receptor (EGFR), urokinase plasminogen activator receptor and integrin  $\alpha v \beta 3$ ).

Weissleder teaches at [0075] and Table 2 of the specification, particular enzymes associated with particular disease states, wherein the probes of Weissleder would be useful. Weissleder is silent on cathepsin L, HER2/epidermal growth factor receptor (EGFR) and integrin  $\alpha v \beta 3$ . Weissleder lists several disease associated with caspases, but does not specify lung cancer, nor does he associate caspase-3 specifically (of the various caspases) with lung cancer.

Similarly, whilst Weissleder mentions urokinase plasminogen activator for cancer, he does not particularly identify lung cancer.

Present amended claim 1 is therefore believed novel over Weissleder. Dependant claims 4, 6-8 and 11 are also therefore, by definition, believed novel over Weissleder. The novelty rejection based on Weissleder should therefore be withdrawn.

#### 4.2 Klaveness (US 6,610,269).

Claims 1-9 and 12 stand rejected under 35 USC 102(b) as being anticipated by Klaveness *et al.* to US 6,610,269 (Klaveness).

The Examiner has thus effectively already acknowledged that claim 10 is novel over Klaveness. Since amended claim 1 is based on the method of claim 10, amended claim 1 is believed novel over Klaveness. Dependant claims 4, 6-8 and 11 are also therefore, by definition, believed novel over Klaveness.

The novelty rejection based on Klaveness should therefore be withdrawn.

#### 4.3 Luiken (US 2001/0055566).

Claims 1-3 and 6-13 stand rejected under 35 USC 102(b) as being anticipated by Luiken to US 2001/0055566 (Luiken).

Applicants point out, as for Klaveness (4.2 above), the Examiner has effectively already acknowledged that the method of claim 10 is novel over Luiken. Since that method forms the basis of revised claim 1, applicants contend that logically currently amended claim 1 is novel over Luiken. Applicants note in this regard that Luiken discloses targeting somatostatin receptors *via* a somatostatin peptide. This approach to targeting is also outside the biological targets of amended claim 1. Hence, amended claim 1 is also believed novel over Luiken. Dependant claims 4, 6-8 and 11 are also therefore, by definition, also believed novel over Luiken.

The novelty rejection based on Luiken should therefore be withdrawn.

#### **5. Double Patenting.**

Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of co-pending applications 10/573604, 10/573606, 10/582679, 10/582680 and 10/582842.

Applicants believe that the present amendment limiting to a method of imaging, now distinguishes the subject matter, so that this provisional rejection no longer applies. In the event, however, that the objection is maintained and the present claims are allowed, Applicants will consider filing a terminal disclaimer as necessary.

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**CONCLUSION**

Applicants respectfully hold that the claims submitted herewith fulfill the requirements of a patentable invention and that all rejections and objections be withdrawn and claims 1, 4, 6-8, and 11 be allowed.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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